

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450**

Appl No.:	10/648,975	Confirmation No. 4147
Applicant:	Dusan Miljkovic	
Filed:	August 26, 2003	
TC/A.U.:	1616	
Examiner:	Choi, Frank I.	
Docket No.:	100700.0016US1	
Customer No.:	24392	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.132**

I, the undersigned, Zbigniew Pietrzkowski, hereby declare as follows:

1. I have been a Ph.D. level scientist and principal investigator for over 20 years.
2. I am presently employed as Scientist.
3. I have been informed that claims in the above-referenced application have been rejected based on various grounds. I believe that the rejection is inappropriate as follows:
  - 3.1. The examiner stated on page 6, line 15 et seq. that no evidence was provided to support that the person of ordinary skill in the art would be disincentivized to use complexes in which boron is tightly bound as one would not expect boron to be bioavailable.

I disagree. It is common knowledge in the art that complexes with relatively high association constant will retain the ligand with high affinity. Therefore, one would not expect boron to be readily bioavailable, and one would therefore be disincentivized to use complexes in which boron is tightly bound.
  - 3.2. The examiner stated on page 6, line 19 et seq. that the boron contained in the complexes is bioavailable.

I disagree. As the boron is bound to the complex with relatively high association constant, boron can not be expected to be bioavailable as stated by the examiner. The attached experimental results (also previously submitted) clearly show that upon oral administration, the boron carbohydrate complex rather than boron/boric acid *per se* is recovered from plasma. Thus, what is bioavailable is the boron carbohydrate complex, but not boron/boric acid *per se* from the boron carbohydrate complex as stated by the examiner.

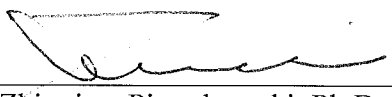
- 3.3. The Naghii, Nielsen, Volpe, and FDA Talk Paper references are concerned with effects of boric acids and/or salts thereof. The compounds of the present claims are concerned with boron carbohydrate complex having relatively high association constant, which are chemically distinct entities, and which are not equivalent with boric acid and/or salts thereof.

As the boron in the boron carbohydrate complex is tightly bound to the carbohydrate portion, and as the boron carbohydrate complex is a chemically distinct entity, there can not be a reasonable expectation that the boron carbohydrate complexes and the boric acid and/or salts thereof will have the same biological effects.

For the above reasons, the examiner's argument that one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the carbohydrate-boron complex would be effective in increasing steroid concentration in humans is incorrect.

4. I hereby declare that all statements made herein of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, Section 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed at July, this 20th day of 2011.

By:   
Zbigniew Pietrzkowski, Ph.D.

Respectfully submitted,  
Fish & Associates, PC

Date: June 22, 2011

By: /Martin Fessenmaier/  
Martin Fessenmaier  
Reg. No. 46697

Fish & Associates, PC  
2603 Main Street, Suite 1000  
Irvine, CA 92614-6232  
Telephone (949) 943-8300  
Fax (949) 943-8358